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EXAMINER	
SAKELARIS, SALLY A	
ART UNIT	**PAPER NUMBER**
1634	

DATE MAILED: 05/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

SM

Office Action Summary	Application No.	Applicant(s)	
	09/857,603	HAJEER ET AL.	
	Examiner	Art Unit	
	Sally A Sakelaris	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14 and 18-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7* is/are rejected.

7)☒ Claim(s) *8-14 and 18-20* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☒ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

Election/Restrictions

Applicant's arguments filed 10/22/03 have been fully considered but they are not persuasive. Applicant's election with traverse of Group I, claims 1-14 and 18-20 is acknowledged. The traversal is on the ground(s) that the claims do in fact define a unified inventive feature. However, the examiner maintains that the two groups are each defined by a different special technical feature; in Group I a nucleic acid while in Group II a modulator represents the special technical feature and as a result, unity of invention is lacking. Each special technical feature has a different structure and function and as a result requires different method steps to accommodate these differences. The lack of unity requirement is maintained and is herein made final.

Specification

A. The attempt to incorporate subject matter into this application by reference to Nelson et al. and Liu et al. is improper because they have not been formally incorporated into the specification. But even if this essential subject matter was formally incorporated into the specification, the incorporation of essential material in the specification by reference to a foreign application or patent, or to a publication is improper. Applicant is required to amend the disclosure to include the material incorporated by reference. The amendment must be accompanied by an affidavit or declaration executed by the applicant, or a practitioner representing the applicant, stating that the amendatory material consists of the same material

incorporated by reference in the referencing application. See *In re Hawkins*, 486 F.2d 569, 179 USPQ 157 (CCPA 1973); *In re Hawkins*, 486 F.2d 579, 179 USPQ 163 (CCPA 1973); and *In re Hawkins*, 486 F.2d 577, 179 USPQ 167 (CCPA 1973). Appropriate correction is required.

B. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code(Pg. 27, for example). Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

C. On page 14 line 14, it is noted that the specification reads "the base at potion –400", when it is assumed that applicant intended to recite "position". Appropriate correction is required.

Drawings

Applicant should note that in FIG. 4, Applicant's description of the gel; "Lanes 2, 4, 6, & are homozygote wild types" appears to be missing a number following the "&" symbol. Appropriate correction is required.

Claim Objections

Claims 8-14 and 18-20 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from any other multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claims 8-14 and 18-20 have not been further treated on the merits. Claims 1-7 are examined herein.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 1-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. Claims 1-7 are indefinite over the recitation of "the RANTES gene promoter". There is insufficient antecedent basis for this limitation in the claim. It is therefore not clear to which RANTES gene promoter the claim is referring. Applicant should clarify to what promoter and to what RANTES gene the claim refers.

B. Claims 1-7 are indefinite. Claim 1 is drawn to a method for diagnosing or detecting a predisposition to a disease or disorder associated with abnormal RANTES gene expression. However, the final process step is one of examining the RANTES gene promoter to detect the presence of a genetic polymorphism. Accordingly, it is unclear as to whether the claim is intended to be limited to methods for detecting the presence of a genetic polymorphism in the RANTES gene promoter or just for diagnosing or detecting a predisposition to a disease or disorder associated with abnormal RANTES gene expression as referred to in the preamble. Applicants should amend the claim to indicate how the step of detecting the presence of a genetic polymorphism in the RANTES gene promoter results in the diagnosis or detection of a predisposition to a disease or disorder.

C. Claims 4-7 are indefinite over the recitation of "relative to the transcription start site of Nelson et al." It is not clear to what transcription start site the claim is referring. The reference, although not incorporated by reference see above objection, references many sequences that contain the promoter region around –400 of the RANTES gene. For example, Figure 7 describes

at least 3 promoter-reporter constructs that contain the around –400 region. It is therefore not clear to what sequence in the reference the claim is referring.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-7 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

For completeness and clarity an analysis of the factors that lead to the conclusion of lack of enablement is provided.

Scope of the Claims and Nature of the Invention

The rejected claims are drawn to a method for diagnosing or detecting a predisposition to any disease or disorder associated with abnormal RANTES gene expression through the detection of genetic polymorphisms in the RANTES gene promoter.

Teachings in the Specification, Direction Provided and Working Examples

The specification provides only am improper reference to a sequence from Nelson et al. The specification does not claim a single nucleotide polymorphism that is characteristic to a specific SEQ ID NO. The specification states that the "preferred positions on the RANTES promoter for examination for polymorphisms are positions –28 and –400 in relation to the transcriptional start site according to the sequence published in Nelson et al, supra. It has come to light that the sequence published in Nelson et al., supra is incorrect and a new sequence for RANTES has been disclosed (Lui et al. PNAS). The new Lui sequence for RANTES contains some insertions relative to the Nelson sequence and this has resulted in a renumbering of the site

of the –400 polymorphism to –403. The site of the –28 polymorphism remains unchanged"(Pg. 4). In example 1, Pg. 14, the specification teaches that "the presence of the RANTES promoter –400 polymorphism (Nelson sequence) (the A allele) was determined in certain groups, to show the link between the presence of the polymorphism and two conditions associated with abnormal RANTES expression, that is asthma and protection from HIV". On page 17 and in Figure 5, the specification teaches that "as shown in the attached table (figure 5) in the asthmatic group the heterozygous AA polymorphic frequency was found to be increased in atopic asthmatics and asthmatics. Furthermore, in the group exposed to HIV infection, there was a significant increase in the AA frequency in exposed uninfected individuals only"(Pg.17). It should be noted that it is not clear what the population is that is being tested in this example. The table on the top of page 15, teaches only that the "HIV-exposed-uninfected" population are the partners of HIV+ve patients for Haemophilia, but nothing more is known about this population. Next, in example 2, there is simply no conclusion about the data concerning the –28 polymorphism present in the specification. In example 3, genotype frequencies were compared between normal blood donors and two groups of participants in the Multicenter AIDS Cohort Study (MACS) of homosexual men: 1) HIV+ participants and 2) highly exposed, uninfected participants(EU). On page 25 the specification teaches that "collectively, these data strongly suggest that the 403G allele may confer protection relative to the –403A allele for homosexual transmission of HIV". It is not clear in the specification how these results from example 1 and example 3 enable the claim drawn to a method for diagnosing or detecting a predisposition to any disease or disorder associated with abnormal RANTES gene expression through the detection of genetic polymorphisms in the RANTES gene promoter. Especially given the specification's teaching that the "A" allele at position –400(Nelson) or –403(Lui) has opposite effects on its ability to protect from HIV. In example 1, the A allele is associated with protection from HIV. In example 3, the G allele at position –400(Nelson) or –403(Lui) is associated with protection from HIV. It is unclear what SNP at position –400(Nelson) or –403(Lui) confers a protection from HIV, in what patient population, and in association with the presence/absence of what other SNPs. There appears to be no data that correlated the presence or absence of a SNP at position –28 with any disease state. With respect to the asthma data, it is not clear how significant any result described in Example 1 and in Figure 5 is without the inclusion of any p-values and data

about their population tested. The specification includes no examples or guidance as to any other particular disease or specific phenotype with which the polymorphism(s) might be associated. Beyond a recitation of uses for the claimed nucleic acids in general research methods the specification does not provide any further guidance for using the claimed nucleic acids.

State of the Art and Level of Unpredictability

The prior art does not provide any specific guidance with regard to the instantly claimed methods used to diagnose or detect a predisposition associated with abnormal RANTES gene expression by detecting the nucleic acids of the RANTES gene promoter, nor with the particular polymorphism located at position 400 or 28 being correlated with a disorder associated with abnormal RANTES gene expression. There is a large body of knowledge in the prior art related to polymorphisms in general, and their association with diseases or disease states. The art is highly unpredictable with regard to the functionality of polymorphic sites in genomic DNA. After a screening assay identifies polymorphisms, it is unpredictable whether any such polymorphisms would be associated with any phenotypic trait, such as a disease state or a physiological state. For example, Hacker et al. were unable to confirm an association between a gene polymorphism and ulcerative colitis in a case where prior studies suggested such a relationship would exist since the relationship had been identified in a different population (Gut, 1997, Vol. 40, pages 623-627). Even in cases where an association between a particular gene and a disease state is known to exist, such as with the LPL gene and heart disease risk or the p-globin gene and sickle cell anemia, researchers have found that when using SNP (single nucleotide polymorphism analysis) it was difficult to associate SNPs with disease states or to even identify key genes as being associated with disease (Pennisi, Science, 281 (5384):1787-1789). Finally, in some cases where multiple polymorphisms are identified in a gene, some of these are demonstrated to be disease associated and some are not. Blumenfeld et al. (WO 99/52942) disclose a number of polymorphisms in the FLAP gene. While Blumenfeld et al. were able to demonstrate that some of these polymorphisms are associated with patients having asthma but some of these are not (see Figure 3). For example, the marker 10-35/390 was demonstrated to be associated with asthma, with a p value of 0.00229, while the marker 10-33/327 was determined to not have a statistical association with asthma (p=0.294). Thus, even for SNPs within the same gene, it is highly unpredictable as to whether a particular marker will

be disease associated. Furthermore, Altshuler teaches that much unpredictability is involved in correlating genetic polymorphisms and disease if the population's make-up is not considered. A perfect example is with the controversial association of the A1 allele of the D2 dopamine receptor with alcoholism. Initially, a strong association was reported. Further investigation failed to demonstrate linkage however, and revealed that the frequency of the A1 allele varies widely between ethnic groups. Thus the observed association is most likely explained by differences in the contributions of subpopulations to the groups of case patients and controls, rather than by a physiologic effect of the genetic variant. As such, applicant's apparent discrepancy in the role of the A allele at position –400, could in fact be attributed to this sort of population admixture.

The post filing date art further corroborates the unpredictability at hand in the association of SNPs, especially those located in RANTES(aka CCL5) –403 and –28 with disease. Chen et al teach RANTES (aka CCL5) SNPs at –403 and –28 in patients with Behcet's disease, a systemic form of an inflammatory condition known as uveitis. Chen et al. teach that "there was no association between any SNP and disease"(abstract). "However, when segregated on the basis of gender the CCR5 –403AA genotype was only found in male patients with BD"(Abstract), thus contributing to the unpredictability involved in associating SNPs and disease states.

Determining how to use the claimed polynucleotides as asserted by applicant, for example for the diagnosis of disease, requires the knowledge of unpredictable and potentially non-existent associations between the polymorphism and any disease state. Even if the claimed polymorphism is in some way associated with HIV protection or asthma, it is difficult (if not impossible) to know or predict from the teachings of the specification which disease or how the polymorphism is associated. That is, it is unpredictable as to whether the presence of a particular allele the polymorphism would confer a higher or lower likelihood of having the disease. In this case, the possible uses for the claimed methods are undefined, beyond the suggestion that they can be used to detect a disease associated with the polymorphism.

Quantity of Experimentation

The quantity of experimentation required to discover how to use the instant invention is very high. In order to use the claimed invention as asserted by the specification, one would have to establish a relationship between the polymorphism at every nucleotide of every

RANTES promoter-containing sequence and some disease state, some disease treatment method, or other relevant phenotypic state. In order to obtain the type of information necessary to practice the claimed invention, one would be required to undertake the screening of hundreds or thousands of patients as well as possible hundreds of diseases or pharmaceutical agents. Even if such experiments were undertaken, it would still be unpredictable as to whether any associations would be detected, in light of the unpredictability of such associations, as already discussed. Thus, while one could perform further research to determine whether applicant's polynucleotides would be useful in disease detection and/or treatment, it is unknown as to what the outcome of such research might be and as to whether any quantity of experimentation would result in the identification of an association between the polymorphism and any disease or condition.

Conclusion

Thus, in light of the nature of the invention, the state of the art, the high level of unpredictability in the art, the lack of direction or working examples in the specification, and the high quantity of experimentation that would be required to practice the claimed invention, it is concluded that undue experimentation would be required to use the instantly claimed invention. Thus, although the specification certainly enables one to make the claimed nucleic acids, it would require undue experimentation in order to determine how to use in a way that is specific and substantial with regard to the claimed invention.

3. Claims 1-7 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification improperly discloses the sequence from Figure 6 of Nelson et al. that correspond to DNA sequence and consensus elements of the RANTES immediate upstream region. Claims 1-7 are directed to encompass a method of detecting the presence of any polymorphism in the RANTES gene promoter and in any region around –400 or –28, that could

be characterized by the presence/absence of any nucleotide. Furthermore, the claims encompass any version of the RANTES gene promoter available(Presently, NCBI carries 54 sequence references that contain this claimed region), including deletion constructs and any splice variant. As the sequences are of different lengths, so are the nucleotides referenced by an arbitrary –400 and –28 sort of position description. Clearly, this large genus of possible RANTES promoter regions in which any SNP in any position is present, is not presently described in the specification. Even furthermore, the genus includes any deletions, additions, resulting frameshifts, transitions and transversions in any version of the RANTES promoter sequence at any nucleotide position. Therefore, as no structure is present, ie. it is not clear what RANTES sequence is being claimed, what single nucleotide polymorphism is being claimed in it and at what position any of these SNPs are located, it is not clear what resulting structure will occur for the practice of claims 1-7. Reading these claims as broadly as they are written, one could interpret that they encompass every version of the RANTES promoter region and each and every variant that could result from any genetic polymorphism. A review of the full content of the specification indicates that the sequence of Nelson et al. and all aforementioned variations, are essential to the operation and function of the claimed invention. None of these sequences meet the written description provision of 35 USC 112, first paragraph. The specification provides insufficient written description to support the genus encompassed by the claim.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

With the exception of a G/A polymorphisms at position –400 and a C/G polymorphism at position –28 of the sequence in Figure 6 of Nelson et al., the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The nucleic acid itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and

Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

> ...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966.
>
> An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. *Fiers v. Revel*, 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." Id. at 1170, 25 USPQ2d at 1606.
>
> The named ORF is not itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for isolating and characterizing cDNA sequences from *E. grandis*, there is no further information in the patent pertaining to that cDNA's relevant structural or physical characteristics; in other words, it thus does not describe *E. grandis* cDNA. Describing a method of preparing a cDNA or even describing the protein that the cDNA encodes, as the specification does, does not necessarily describe the cDNA itself. No sequence information indicating which nucleotides constitute *E. grandis* cDNA appears in the application. Accordingly, the specification does not provide a written description of the invention of claims 1, 4, and 6-15.

Therefore, none of the sequences encompassed by the claim meets the written description provision of 35 USC 112, first paragraph. The species specifically disclosed are not representative of the genus because the genus is highly variant. Applicant is reminded that Vas-

Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115.)

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Nelson et al.(Journal of Immunology, 1993).

With regard to claim 1, Nelson et al. on page 2608 teach sequencing the DNA sequence and consensus elements of the RANTES immediate upstream region including the promoter in an in vitro method. With regard to the preamble of this claim, it is not deemed that the preamble breathes life in to the claim, since there is no process step that requires diagnosing or detecting a predisposition to a disease or disorder.

With regard to claims 2 and 3, Nelson et al. teach that a human placental genomic DNA bacteriophage library was the source of the sequenced DNA and was screened with the 411 nucleotide RANTES cDNA fragment(Pg. 2602).

With regard to claims 4 and 6, Nelson et al. teach the in vitro method of sequencing the RANTES gene promoter region around –400 and –28 respectively, relative to the transcription site of Nelson et al.

With regard to claims 5 and 7, as there is no requirement in the claim that the presence of a polymorphism actually be associated with a predisposition or a disease, the only requirement of determining the sequence at the –400 and –28 positions respectively, is taught in Nelson et al.'s Figure 6.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sally A Sakelaris whose telephone number is 571-272-0748. The examiner can normally be reached on M-Fri, 9-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

5/6/2004

Sally Sakelaris

JEFFREY FREDMAN
PRIMARY EXAMINER